

Sosei Heptares' partner Neurocrine Biosciences Initiates Phase 1 Clinical Study Evaluating Effects of NBI-1117570 in Healthy Adults

- *NBI-1117570 is an investigational, oral, muscarinic M1/M4 selective dual agonist discovered by Sosei Heptares that may have the potential to treat neurological and neuropsychiatric conditions*
- *NBI-1117570 is the second compound to advance into clinical development from a portfolio of selective muscarinic receptor agonists licensed by Sosei Heptares to Neurocrine following NBI-1117568, an oral, selective muscarinic M4 receptor agonist, which is in Phase 2 clinical trials as an investigational treatment for schizophrenia*

Tokyo, Japan and Cambridge, UK, 12 September 2023 – Sosei Group Corporation (“the Company”; TSE: 4565), has been notified by its partner Neurocrine Biosciences Inc. (“Neurocrine”; Nasdaq: NBIX), a leading neuroscience-focused biopharmaceutical company, that it has initiated its Phase 1 first-in-human clinical study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of investigational compound NBI-1117570 in healthy adult participants. NBI-1117570 is an investigational, oral, muscarinic M1/M4 selective dual agonist that may have the potential to treat neurological and neuropsychiatric conditions and was developed utilising Sosei Heptares' structure-based drug design platform.

“Initiation of this Phase 1 study represents an important step forward for NBI-1117570, a potentially first-in-class, orally active, selective investigational dual M1/M4 agonist,” **said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences.** “The selectivity profile of NBI-1117570 in targeting M1 and M4 receptors may provide an opportunity to treat symptoms of both psychosis and cognition across a broad range of neurological and neuropsychiatric conditions.”

Matt Barnes, President of Heptares Therapeutics and Head of UK R&D, said: “We are delighted that Neurocrine is progressing this unique M1/M4 selective agonist into clinical development to target important unmet medical needs in neurological and neuropsychiatric disorders. NBI-1117570 is the second candidate to advance into clinical trials from the portfolio of selective muscarinic receptor agonists discovered and licensed by Sosei Heptares to Neurocrine in 2021. We look forward to reporting further progress from these and potentially other candidates under this highly productive partnership.”

The clinical development milestone achieved with NBI-1117570 as announced does not trigger a milestone payment from Neurocrine to Sosei Heptares under the terms of the 2021 agreement between the companies. Milestone payments, under the agreement, are payable upon the

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achievement of multiple, defined development events for each program. Sosei Heptares will announce the receipt of any milestone payments in accordance with TSE reporting requirements.

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About NBI-1117570

NBI-1117570 is an investigational, oral, muscarinic M1/M4 dual agonist. Muscarinic receptors are fundamental to activating signaling pathways in the brain. There are five muscarinic acetylcholine receptors involved in neurotransmission, two of which are selectively targeted by NBI-1117570 (M1 and M4), with M1 validated as a potential drug target in cognition and M4 in psychosis for clinical drug development. Neurocrine Biosciences acquired the rights to develop and commercialize NBI-1117570 from Sosei Heptares.

About the Agreement with Neurocrine Biosciences

Sosei Heptares and Neurocrine BioSciences entered a collaboration and licensing agreement in November 2021 to develop novel muscarinic receptor agonists for the treatment of schizophrenia, dementia and other neuropsychiatric disorders.

Under the terms of the agreement, Neurocrine gains development and commercialization rights to a broad portfolio of novel clinical and preclinical subtype-selective muscarinic M4, M1 and dual M1/M4 receptor agonists discovered by Sosei Heptares. Neurocrine is responsible for development costs associated with the programs globally, except for M1 agonists being developed in Japan. Sosei Heptares retains rights to develop M1 agonists in Japan for any indication, with Neurocrine receiving co-development and profit share options.

Sosei Heptares is eligible to receive R&D funding plus development, regulatory and commercial milestones of up to US\$2.6 billion, with further product royalties, provided the criteria under the agreement are satisfied.

About Neurocrine Biosciences

Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit [neurocrine.com](https://www.neurocrine.com), and follow the company on [LinkedIn](#), [Twitter](#), and [Facebook](#).

**in collaboration with AbbVie*

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About Sosei Heptares

Sosei Heptares is a fully integrated biopharmaceutical company focused on bringing life-changing medicines based on world-class science to patients globally. Our vision is to become one of Japan's global biopharmaceutical champions.

Our global business combines our world-leading GPCR-targeted StaR[®] technology, structure-based drug design and early development capabilities in the UK with a highly experienced clinical development capability and a commercial operation in Japan.

We are leveraging these capabilities to generate and advance a broad and deep pipeline of novel medicines across multiple therapeutic areas, including neurology, immunology, gastroenterology and inflammatory diseases. We intend to develop these opportunities for patients in Japan and globally both internally and through our partnerships with global biopharmaceutical companies and emerging technology companies.

Sosei Heptares operates from key locations in Tokyo and Osaka (Japan), London and Cambridge (UK) and Seoul (South Korea).

"Sosei Heptares" is the corporate brand and trademark of Sosei Group Corporation, which is listed on the Tokyo Stock Exchange (ticker: 4565). Sosei, Heptares, the logo and StaR[®] are trademarks of Sosei Group companies.

For more information, please visit <https://soseiheptares.com/>

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Sosei Group Corporation Forward-Looking Statements

This press release contains forward-looking statements, including statements about the discovery, development, and commercialization of products. Various risks may cause Sosei Group Corporation's actual results to differ materially from those expressed or implied by the forward-looking statements, including: adverse results in clinical development programs; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialize



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products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialization activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Neurocrine Biosciences, Inc. Forward-Looking Statement

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements related to the potential benefits of NBI-1117570. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks that clinical development activities may not be initiated or completed on time or at all, or may be delayed for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; our future financial and operating performance; risks associated with our dependence on third parties for development, manufacturing, and commercialization activities for our products and product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks that the potential benefits of the agreements with our collaboration partners may never be realized; risks that our products, and/or our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks associated with U.S. federal or state legislative or regulatory and/or policy efforts which may result in, among other things, an adverse impact on our revenues or potential revenue; risks associated with potential generic entrants for our products; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.